

Idaho's Approach to the Distribution of Pharmaceuticals for the Prevention and Treatment of COVID-19 in Non-Hospitalized Patients

Updated: January 31, 2022

Overview

This document provides an overview of Idaho's approach for coordinating the distribution of pharmaceuticals for the prevention and treatment of COVID-19 for non-hospitalized patients. Specifically, this document describes Idaho's approach to the distribution of:

- antiviral medications for treatment of COVID-19
- monoclonal antibodies for treatment of COVID-19
- monoclonal antibodies for pre-exposure prophylaxis (prevention) of COVID-19

This document addresses the distribution of COVID-19 therapeutics coordinated by public health officials. It does not address distribution for hospitalized patients, which is not coordinated by public health.

The Idaho Division of Public Health (DPH) is coordinating with local public health districts and federal partners to ensure Idahoans have access to therapeutics as they become available. DPH staff participate in multiple calls weekly with federal partners to ensure we are receiving the latest information and utilizing our allocated medications appropriately.

Limited supply continues to be our biggest constraint in offering these therapies to Idahoans.

For example, antivirals are allocated every two weeks. Idaho's two-week allocation of antivirals for the timeframe including the weeks of January 10th and January 17th was enough to treat only the following numbers of patients:

Molnupiravir (oral antiviral)	Paxlovid (oral antiviral)
1600	400

Monoclonal antibodies are allocated weekly. Idaho's weekly allocation of monoclonal antibodies for the week of January 17th was enough to treat or provide prevention to the following numbers of patients:

Sotrovimab (monoclonal antibody for treatment)	EVUSHELD (long-acting monoclonal antibody for pre-exposure prophylaxis)
102	360

Allocations of therapeutics to Idaho healthcare providers, pharmacies, and treatment sites are made by DPH weekly (monoclonal antibodies) or every other week (oral antivirals) based on requests, geographic distribution, and demonstrated use/on-hand inventory as reported by the providers or pharmacies. These therapies are currently prioritized for high-risk patients as defined in this document. The general approach to distribution in the state is:

- Oral antiviral medications are allocated to pharmacies, as these are medications that can be prescribed for use at home
- Treatment monoclonal antibodies are allocated to providers such as clinics, hospitals, and healthcare systems able to provide outpatient intravenous infusions or subcutaneous injections to high-risk populations
- Preventive monoclonal antibodies are currently being allocated to cancer treatment centers and will next be allocated to clinics serving patients taking immunosuppressive medications

Sites receiving these therapeutics have been encouraged to work with other providers in their communities to allow referrals of patients meeting the criteria established for receipt of the therapeutics.

Oral Antiviral Medications

Two recently authorized antiviral medications are being allocated to Idaho for use in persons at high risk of severe disease as outlined in the following Emergency Use Authorization Fact Sheets:

• Molnupiravir: https://www.fda.gov/media/155054/download

Paxlovid: https://www.fda.gov/media/155050/download

To date, doses of these two antivirals have been allocated to pharmacies that are part of the federal retail pharmacy partnership program, as per federal recommendations, and include at least one pharmacy in each of the local public health districts. A list of pharmacies receiving oral antivirals has been made available and sent to prescribing healthcare providers statewide via our Health Alert Network (HAN) messaging system. As additional supplies of oral antivirals arrive in Idaho, we will expand sites receiving the medications and send updates to providers via the HAN messaging system with an updated list of pharmacy locations and instructions on how to work with receiving pharmacies to confirm availability. Supply as of this date remains extremely limited.

In addition, the FDA approved remdesivir for outpatient use on January 21st.

Remdesivir for outpatients: https://www.fda.gov/news-events/press-announcements/fda-takes-actions-expand-use-treatment-outpatients-mild-moderate-covid-19

We are exploring whether remdesivir may soon be offered at some of the administration sites already offering therapeutics and have begun communicating with sites to identify and resolve barriers, including ordering of this product directly from their usual suppliers, as it is not provided by the federal government. Several healthcare systems have reported use of remdesivir in the outpatient setting. The manufacturer is only allowing hospital outpatient departments to order

remdesivir as of this date, but that is expected to change in the future to allow use in other outpatient settings.

Monoclonal Antibodies for Treatment

Three monoclonal antibodies with FDA authorization for treatment of COVID-19 were previously available for use in the U.S. However, two of the three monoclonal antibodies are considered ineffective against the Omicron variant, which is now the overwhelmingly dominant variant nationwide and in Idaho. Therefore, the FDA limited use of these two monoclonal antibodies on January 24th, stating "Because data show these treatments are highly unlikely to be active against the omicron variant, which is circulating at a very high frequency throughout the United States, these treatments are not authorized for use in any U.S. states, territories, and jurisdictions at this time." https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-limits-use-certain-monoclonal-antibodies-treat-covid-19-due-omicron

Due to this change, patients who are diagnosed with mild-to-moderate COVID-19 and are at high risk of severe outcomes are currently eligible for only one type of monoclonal antibody (sotrovimab) at various clinics and treatment centers throughout the state.

Sotrovimab: https://www.fda.gov/media/149534/download

Sotrovimab is in extremely short supply. DPH has ordered ALL doses of sotrovimab made available to Idaho and has allocated the doses to clinics and healthcare systems in each of the seven local public health districts to try to maximize geographic equity.

Receiving providers have also been recommended to review and take into consideration the NIH COVID-19 Treatment Guidelines Panel's Statement on prioritization when there are logistical or supply constraints. These guidelines include a link to the CDC page which lists patient characteristics with a higher risk of severe outcome, which include:

- age ≥65y
- cancer
- obesity with BMI >30 kg/m2
- cardiovascular disease
- pregnancy
- diabetes
- significantly reduced kidney function
- chronic lung disease
- chronic liver disease
- smoking

Monoclonal antibodies for pre-exposure prophylaxis

A monoclonal antibody combination product, EVUSHELD, is now available in limited supply for <u>pre-exposure prophylaxis</u> in certain patients.

EVUSHELD is indicated for persons:

• Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2, and either:

- have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination, or
- vaccination with any available COVID-19 vaccine is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).

Given the severely constrained supply, EVUSHELD has been initially prioritized for highly immunocompromised individuals, and initial allocations have been entirely distributed to cancer treatment centers. These cancer centers have been asked to also administer to EVUSHELD to other highly immunocompromised individuals, such as organ transplant patients, upon referral from a provider. As cancer centers begin to meet their needs, other immunocompromised patients such as those on immunosuppressive medications will be prioritized, and providers serving those patients will be offered supplies of EVUSHELD.

Communication with Healthcare Providers and the Public

In light of the limited supply, it is challenging to communicate clearly to providers and the public about where to locate these therapeutics; providers and pharmacies may have some available at certain times but may then quickly use up their allotment. Providers need reliable information on where their patients can receive monoclonal antibodies and which pharmacies carry the oral antivirals.

The HHS COVID-19 Therapeutics Locator website provides data on allotted and available courses of some therapeutics https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/ and lists locations that have received molnupiravir, Paxlovid, or EVUSHELD. However, this site is not yet tracking allocated or available courses of sotrovimab. DPH sent a HAN message to Idaho healthcare providers the week of January 3, 2022 on how to access the oral antivirals.

More recently, the state website has been updated with information for providers and the general public.

Links on the site include:

- Idaho Department of Health and Welfare, Side-by-Side Overview of Therapeutics Authorized for Non-Hospitalized Patients, January 13, 2022, available at https://coronavirus.idaho.gov/wp-content/uploads/2022/01/COVID-19 Therapeutics-Overview_Providers_20220113_FINAL.pdf
- U.S. Centers for Disease Control and Prevention, What Clinicians Need to Know About the New Oral Antiviral Medications for COVID, Clinician Outreach and Communication Activity (COCA) Call, January 12, 2022, available at https://coronavirus.idaho.gov/wp-content/uploads/2022/01/What-Clinicians-Need-to-Know-about-the-New-Oral-Antiviral-Medications-for-COVID-19.pdf
- U.S. Department of Health and Human Services (HHS) COVID-19 Therapeutics Locator, available at https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/

Idaho will prioritize the equitable distribution of and access to COVID-19 therapeutics throughout the state and will help ensure these limited resources reach vulnerable and hard-hit communities. We are working with our local public health departments, infusion centers, cancer

centers, hospitals and clinics to allocate therapeutics fairly across the state. We are committed to maintaining transparency throughout the process.

